DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-243/S-023

Solvay Pharmaceuticals
Attention: K. Gary Barnette, Ph.D.
Director, Regulatory Affairs
901 Sawyer Road
Marietta, Georgia 30062

06 SEP 2001

Dear Dr. Barnette:

We acknowledge receipt of your supplemental new drug application dated August 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Luvox (fluvoxamine maleate) Tablets.

Reference is also made to an Agency letter dated May 17, 2001, requesting revisions to the Luvox labeling.

This "Changes Being Effected" supplemental new drug application provides for the addition of a subsection entitled **Mexiletine** under the **WARNINGS-Other Potentially Important Drug Interactions** section as requested in the Agency letter dated May 17, 2001.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 16, 2001/Label Code 1280/1285 22E), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research